REMARKS

Applicants noted in their responsive Amendment filed May 7, 2001 that the Information Disclosure Statement mailed April 20, 2000 did not appear to have been considered by the Examiner. The Action mailed July 31, 2001 includes only Page 8 of the eight pages of references included in the April 20 Information Disclosure Statement. Applicants respectfully request that the Examiner confirm that the other seven pages of references included in the April 20 Information Disclosure Statement have been considered by him.

In an Amendment and Response to Restriction Requirement mailed October 11, 2000, Applicants elected the species of FIGS. 23-27 and noted that the embodiment shown in FIGS. 23-27 has similarities to other embodiments previously disclosed in the application. Applicants further indicated that Claims 14-30 read on the species disclosed in FIGS. 23-27.

The specification has been objected to because it is the Examiner's position that Applicants have evoked sixth paragraph, means-plus-function language to define Applicants' invention. Applicants have been required to amend the specification to explicitly state what structure, materials and acts perform the function recited in the claim elements. Claims 14-30 have been similarly rejected. In this regard, many of the claims have been amended to delete the word "means" therefrom. In addition, the specification has been amended to make clear what previously defined structure in the specification performs certain functions contained in the claims. With these amendments and explanations, it is assumed that the foregoing rejections to the specification and claims will be withdrawn.

Claims 14-18 and 23-28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Orandi (U.S. Patent No. 4,524,770). Claims 19-22 and 29-30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Orandi in view of LeVeen (U.S. Patent No. 3,991,770). Reconsideration of these claims is respectfully requested.

Orandi discloses an endoscope injection needle. Tool 10 is comprised of a needle 12 fastened to a semi-rigid shaft 14 having a conduit element or flexible tube 16 extending therethrough. Col. 4, lines 33-35. Needle 12 is fastened at one end of shaft 14 in a conventional way. Col. 4, lines 47-48. Flexible tube 16 is fastened to shaft 14 in a conventional way. In this fashion, tube 16 and shaft 14 provide a conduit from the forcing mechanism such as a syringe (not shown) to needle 12. Col. 4, lines 56-57. FIGS. 7 and 8 show a tool 10 used in a

representative urological operative instrument 30, namely a resectoscope. Col. 6, lines 27-29. To install a tool 10 in resectoscope 30, instrument 30 may be in or out of the patient. Tool 10 is inserted in a retrograde fashion by passing needle 12 and shaft 14 through header 86. With end portion 34 between header 86 and body 84, shaft 14 is bent at slot 22 so that it extends away from body 84 and may be connected to luer lock 106 for connection to a syringe. The portion of shaft 14 within sheath 78 is then moved toward body 84 so that end portion 34 extends into passage 104 allowing end portion 34 to be clamped by clamping mechanism 28. By extending tool 10 into passage 104 so that end portion 34 of end piece 18 contacts connector 42, tool 10 may be used as an electrode when connector 42 is appropriately connected to an electrical energy source. Tool 10 is now operable by instrument 30 simply by operating working element 74 and moving the tip of needle 12 longitudinally within the objective field of view of instrument 30. Col. 6, line 66 to Col. 7, line 15.

Claim 14 has been amended to make it more readable and to include a limitation of the type found in former Claim 16. As so amended, Claim 14 is patentable by calling for a treatment device assembly of the type set forth therein having, among other things, a needle having a hollow core, a cannula for slidably receiving said needle so as to guide said needle, a control mechanism for extending and retracting said needle and means for interlocking said assembly to the housing of said endoscopic surgical instrument so as to extend said needle and cannula through the conduit of said endoscopic surgical instrument.

Contrary to the assertion of the Examiner, Orandi does not disclose an assembly as called for in Claim 14 having a cannula for slidably receiving a needle so as to guide said needle. As noted above, needle 12 of the Orandi device is disposed directly within sheath 78 and not within a cannula which is disposed in the sheath 78.

Claims 15-23 depend from Claim 14 and are patentable for the same reasons as Claim 14 and by reason of the additional limitations called for therein.

Claim 24 is patentable by calling for a medical treatment device of the type set forth therein having, among other things, a guide cannula mounted in an at least one passageway of an elongate probe member and having proximal and distal extremities with the distal extremity of the guide cannula being in the vicinity of the distal extremity of the elongate probe member, the guide cannula having an opening in the distal extremity and a lumen extending from the

proximal extremity to the opening in the distal extremity, a needle slidably disposed in the lumen of the guide cannula. Orandi does not disclose a guide cannula mounted in a passageway of an elongate probe member.

Claims 25-30 depend from Claim 24 and are patentable for the same reasons as Claim 24 and by reason of the additional limitations called for therein.

Claims 14-30 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims in U.S. Patent Nos. 6,102,886, 5,848,986, 5,531,677 and 5,409,453. Applicants will address this rejection upon resolution of the prior art rejection discussed above.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

A. The specification has been amended as indicated:

Amend the paragraph beginning on Page 12, line 8 as follows:

One embodiment of the device of this invention uses the urethra to access the prostate and positions RF electrode stylets directly into the tissues to be destroyed. The portion of the stylet conductor extending from the urethra to targeted tissues is enclosed within a longitudinally adjustable sleeve shield which prevents exposure of the tissue adjacent to the sleeve to the RF current supplied by a radio frequency generator. The sleeve movement is also used to control the amount of energy per unit surface area which is delivered by controlling the amount of electrode exposed. Thus the ablative destruction is confined to the tissues targeted for destruction, namely those causing the constriction. Other aspects of the invention will become apparent from the drawings and accompanying descriptions of the device and method of this invention. It will be readily apparent to a person skilled in the art that this procedure can be used in many areas of the body for percutaneous approaches and approaches through body orifices.

Amend the paragraph beginning on Page 20, line 28 and continuing to Page 21, line 20 as follows:

In one mode of operation of the device of this invention with a cystoscope 131, the rod 8 is turned to set the desired exposure of the electrode tip 22. The cystoscope 131 is advanced up the urethra until its end is positioned in a selected location within the prostate. The cannula 4 is then advanced until the flexible tip 14 is positioned at the distal end of the cystoscope 131. The pull wire lever 12 is rotated toward the distal end until the desired curvature of the tip 14 is achieved, that is, positioned to direct the stylet outward through the urethral wall at the desired angle to the target tissue to be ablated. The rod 6 is then pushed in the distal direction until abutment of the slide surface 100 with the abutment surface 102 occurs. Subsequent distal movement of the rod 6 pushes the stylet outward through the urethral wall and to the desired depth in the prostate. RF current from a radio frequency generator is then passed through the electrode to the

exposed distal surface thereof, through the surrounding prostate tissue and to an indifferent skin surface electrode. Passage of the RF current is continued until the desired ablation is achieved, the circuit to the electrode is opened, the rod 6 is pulled in the proximal direction to withdraw the electrode and sleeve from the tissue until it is enclosed in the cannula. The pull wire lever 12 is pulled or rotated in the proximal direction to straighten the tip 14. The cannula 4 and cystoscope 131 are then moved to a different location in the urethra to form another lesion or withdrawn from the urethra.

Amend the paragraph beginning on Page 27, line 26 and continuing to Page 28, line 7 as follows:

FIG. 23 is a side view of an embodiment of this invention with two separate stearable tips for use with a special bridge construction and a standard cystoscope 251. FIG. 24 is a top view thereof. FIG. 25 is a cross-sectional view taken along the line 25--25 of FIG. 24. In this embodiment, the bridge 252 is designed to fit into a bridge receptor (not shown) in a cystoscope 251, which is included within the means of the invention for interlocking the cannula and stylet to the cystoscope. FIG. 26 is a bottom view thereof. FIG. 27 is a cross-sectional side view of the handle showing its essential components. Bridge 252 supports a conventional optic viewing assembly 254 including a conventional, focusing lens 256, light source connector 258 and fiber optic assembly 260. Bridge 252 also includes a receptor for the distal projection 262 of the control handle 264.

B. The following claim has been amended as indicated:

14. (Amended) A treatment device assembly for an endoscopic surgical instrument having a housing and being provided with a conduit comprising:

a) a needle having a hollow core;

b) [means] a cannula for [guiding] slidably receiving said needle so as to guide said needle;

c) a control [structure means] mechanism for extending and retracting said needle; and

d) means for interlocking said assembly to [a] the housing of said endoscopic surgical instrument[,] so as to extend said needle and [means for guiding] cannula through [a single access] the conduit of said endoscopic surgical instrument.

15. (Twice Amended) An assembly as recited in Claim 14 [further comprising means] wherein said cannula includes a curvable surface for deflecting said needle at an angle from a primary axis of said needle.

16. (Amended) An assembly as recited in Claim 15 wherein said [means for deflecting includes said means for guiding having a bendable guiding sheath with] cannula has a bendable portion having a wire enclosed therein having a first end and a second end[,] and said assembly further [comprising means] comprises a finger actuatable mechanism for tensioning said wire[;] whereby when said wire is tensioned by an operator through operation of said [means for tensioning] finger actuatable mechanism, said bendable portion is angled away from a primary axis of said [guiding sheath] cannula and said electrode is deflected away from said primary axis.

17. (Amended) An assembly as recited in Claim [15] 14 wherein said means for [deflecting is a curved end in said means for guiding for directing said needle away from said primary axis] interlocking includes means for removably disposing the assembly [to] within the housing whereby said needle and cannula can be slidably disposed in and removed from the conduit of said endoscopic surgical instrument.

19. (Amended) An assembly as recited in Claim 18 further comprising [means] a radio frequency generator for supplying RF energy to said [assembly] electrode.

20. (Amended) An assembly as recited in Claim 19 [wherein said means for supplying is for supplying RF energy to said electrode for monopolar operation] further comprising an indifferent electrode coupled to said radio frequency generator.

21. (Amended) An assembly as recited in Claim 14 wherein

a) said needle is an RF electrode; and

b) said assembly further comprises [means for application of] a radio frequency generator for supplying RF energy to said electrode for monopolar operation.

22. (Amended) An assembly as recited in Claim 21 [further comprising means] wherein said cannula includes a curved surface for deflecting said electrode at a predetermined angle from a primary axis of said electrode.

24. (Amended) A medical treatment device comprising an elongate probe member having proximal and distal extremities, the elongate probe member having a longitudinal axis and at least one passageway extending from the proximal extremity to the distal extremity, a guide [means] cannula mounted in the at least one [passage] passageway of the elongate probe member and having proximal and distal extremities with the distal extremity of the guide [means] cannula being in the vicinity of the distal extremity of the elongate probe member, the guide [means] cannula having an opening in the distal extremity and a lumen extending from the proximal extremity to the opening in the distal extremity, a needle slidably disposed in the lumen of the guide [means] cannula, the needle being in the form of a tube having an axial lumen extending therethrough, and a control [means] mechanism coupled to the proximal extremity of the elongate probe member and secured to the needle for advancing and retracting the needle relative to the guide [means] cannula.

25. (Amended) A device as in Claim 24 wherein the distal extremity of the guide [means] cannula is [curved] curvable for directing the needle sidewise of the longitudinal axis.

26. (Amended) A device as in Claim 24 wherein the distal extremity of the guide [means] cannula is bendable, an additional control [means] mechanism coupled to the proximal extremity of the elongate probe member for bending the distal extremity of the guide [means] cannula.

30. (Amended) A device as in Claim 29 further comprising [means] a radio frequency generator for supplying radio frequency energy to the radio frequency electrode.